REMARKS

Summary of the Office Action

Claims 5-7, 9-10, 14, and 17 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Pat. Pub. No. 2004/0076984 ("*Eils*").

Claims 8 and 15-16 stand rejected under 35 U.S.C. 103(a) as allegedly obvious over *Eils* in view of U.S. Patent No. 5,516,640 ("*Watanabe et al.*"), as applied to claims 1-7, 9-12, and 14.

Status of the Claims

Claim 5 is amended to correct a minor informality with antecedent basis. Claims 1-4 and 11-13 are canceled. Claims 5-10, and 14-17 are pending.

All Claims are Patentable

35 U.S.C. § 102(e)

Claims 5-7, 9-10, 14, and 17

Claims 8 and 15-16 stand rejected under 35 U.S.C. § 102(e) as allegedly being unpatentable over *Eils*. As a preliminary matter, the Applicant notes that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131. Thus, for this rejection to stand, *Eils* must disclose each and every element as set forth in the claims. However, as described in more detail below, *Eils* does not disclose at least the following aspects of claim 5.

Claim 5 recites, in part, "processing *these values to determine* one or a plurality of *clinical laboratory test items* which *have an influence on the prognosis* of the disease" and "determining *a priority of the items with respect to the prognosis* in a case where there are a plurality of the items." (Emphasis added). The Office Action alleges that the "Examiner respectfully disagrees with Applicant's argument that (A) Eils does not disclose or suggest the determination of a priority of clinical test items for the prognosis of a disease where there are a plurality of test items." (Office Action at p. 7). The Office Action supports this allegation by stating that "Eils discloses and suggests of the use of at least Artificial Neural Networks (ANN),

Bayesian Belief Networks (BBN) and several different clustering approaches for classification or prediction of diseases using many types [of] clinical data (Eils, [0001]-[0018]). *Inherent in the use of and in the definition of* ANN, BBN and clustering technologies and techniques is the ability to determine a priority of clinical test items for the prognosis of a disease where there are a plurality of test items." (Office Action at p. 7) (emphasis added). Applicants respectfully disagree.

Regardless of what might or might not be inherent in the use of and in the definition of ANN, BBN, and clustering technologies and techniques, *Eils* fails to disclose, that *clinical laboratory test values* for the disease and *actual measured values* of the prognosis are processed *to determine* one or a plurality of *clinical laboratory test items* which have an influence on the prognosis of the disease, as claimed. Specifically, paragraphs [0010] – [0016] merely disclose, in part, "optionally automatically generating classification, prediction, association and/or identification data by means of machine learning, and . . . supervised machine learning . . . [T]he *machine learning system* is an artificial neural network learning system (ANN), a decision tree/rule induction system and/or a Bayesian Belief Network" *Eils* at par. [0010] – [0012] (emphasis added). Thus, as *Eils* expressly admits, the foregoing techniques are part of a "*machine learning system*" and, therefore, they cannot be considered as disclosing "*to determine* one or a plurality of *clinical laboratory test items* which have an influence on the prognosis of the disease," because the "*machine learning system*" cannot "*determine* . . . clinical laboratory test items" (emphasis added). Furthermore, even "*generating the data* in the machine learning system" uses "at least one decision tree/rule induction algorithm" *Eils* at par. [0013], which in fact teaches away from the claimed invention which does not "*generat[e] the data*" that is "processed," but rather receives input *of actually measured clinical laboratory test values* for the disease and *actual measured values of the prognosis* into the computer. One of ordinary skill in the art would recognize that to "*generat[e] the data*" using "at least one decision tree/rule induction algorithm," as *Eils* discloses at par. [0013], in fact teaches away from receiving as "*input*" the *actually measured . . . values* as claimed. For at least the foregoing reasons, Applicants respectfully assert that regardless of what might or might not be "[i]nherent in the use of and in the definition of ANN, BBN, and clustering technologies and techniques," *Eils* fails to disclose the foregoing limitations as claimed.

Furthermore, Applicants contest the Office's assertion that "*[i]nherent in the use of and in the definition of* ANN, BBN and clustering technologies and techniques is the ability to determine a priority of clinical test items for the prognosis of a disease where there are a plurality of test items" (Office Action at p. 7) (emphasis added). *Eils* describes the foregoing as "the machine *learning system*." *Eils* at par. [0010] – [0012] (emphasis added). In addition, the data generated "in the machine learning system [using] at least one decision tree/rule induction algorithm" is disclosed in *Eils* as "tumor identification data" and "tumor classification data." *Eils* at par. [0013] – [0015] (emphasis added). In contrast, claim 5 recites, in part, *determining a priority of the items* with respect to the prognosis. (Emphasis added). The "items" whose priority is determined are *clinical laboratory test items* which *have an influence on the prognosis of the disease*, as claimed, not actual identification data or classification data, as *Eils* discloses. (Emphasis added). *Eils* does not disclose *determining* a *priority* of such items, as claimed, but merely uses the above techniques to *generate* data using the machine *learning system*. (Emphasis added).

Furthermore, the generated tumor identification data and tumor classification data cannot be considered *clinical laboratory test items* which have an influence on the prognosis of the disease, as claimed. Interpreting the limitation clinical laboratory test items in view of the limitation of claim 8 which recites *the clinical laboratory test item* with a highest priority *comprising PIVKA*, is convincing evidence that the limitation certainly does not correspond to tumor identification data or tumor classification data. (Emphasis added). Accordingly, for at least the foregoing reasons, Applicants respectfully assert that claim 5 is in condition for allowance. Claims 6-10 and 14-17 are also in condition for allowance at least because of their ultimate dependence on claim 5.

35 U.S.C. § 103(a)

Claims 8 and 15-16

Claims 8 and 15-16 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Eils*, in view of *Watanabe et al*. As a preliminary matter, the Applicant notes that the key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious and all words in a claim must be

considered in judging the patentability of that claim against the prior art. MPEP §§ 2142, 2143.03. Thus, for this rejection to stand, *Eils* in combination with *Watanabe et al.* must disclose each of the limitations of the claims.

As described in detail above, *Eils* fails to disclose each and every limitation of claim 5, which is the base claim for claims 8 and 15-16. Further, *Watanabe et al.* cannot stand alone without *Eils*. Applicants need not address the rejection of dependent claims 8 and 15-16 under 35 U.S.C. § 103(a) because those claims are allowable at least because of their dependency on claim 5. Therefore, Applicants respectfully request that the 103(a) rejection be withdrawn.

Conclusion

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted

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